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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,065	08/22/2003	James H. Brauker	DEXCOM.012A	9709

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EXAMINER	
SINGH, SATYENDRA K	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,065	BRAUKER ET AL.	
	Examiner	Art Unit	
	Satyendra K. Singh	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-250* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-250* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-28, drawn to **a biointerface membrane**, classified in class 623, subclass 23.76, and others.

II. Claims 29-56, drawn to **a sensor head** suitable for use in an implantable device, classified in class 600, subclass 365, and others.

III. Claims 57-85, drawn to **an analyte measuring device** for measuring concentration of an analyte in a body, classified in class 600, subclass 365, and others.

IV. Claims 86-112, drawn to **an implantable glucose sensor** suitable for measuring glucose in a biological fluid, classified in class 600, subclass 365, and others.

V. Claims 113-140, drawn to **a biointerface membrane**, classified in class 623, subclass 23.76, and others.

VI. Claims 141-168, drawn to **a membrane suitable for implantation in soft tissue**, classified in class 623, subclass 23.76, and others.

VII. Claims 169-187, drawn to **a method of monitoring an analyte level**, classified in class 435, subclass 14, and others.

VIII. Claims 188-216, drawn to **a method of monitoring an analyte level**, classified in class 435, subclass14, and others.

IX. Claims 217-250, drawn to **a method of measuring an analyte in a biological fluid**, classified in class 435, subclass 14, and others.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions of groups (I, V and VI) and groups (VII, VIII and IX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compositions of groups (I, V and VI) can be used in materially different processes of using that product such as in the process of drug delivery, cell transplantations, and other biomedical processes, applicable both *in vivo* and *in vitro*.

2. The inventions of groups (I, V and VI) and groups (II, III and IV) are distinct from one another. The inventions of groups (I, V and VI) are drawn to distinct membrane compositions, whereas the inventions of groups (II, III and IV) are directed to distinct products made of distinct components such as a sensor head, an analyte measuring device, and an implantable glucose sensor.

3. The inventions of groups (I, V and VI) are distinct from one another. The inventions of groups I, V and VI are drawn to distinct membrane compositions having distinct structural features/requirements (see instant claims 1, 113, and 141 for detailed recitations). The inventions of group I require the limitation wherein "a substantial number of the interconnected cavities are greater than or equal to about 90 microns in

at least one dimension" which is not required by the inventions of groups V and VI. The invention of groups V and VI are distinct because the invention of group V requires the limitation "wherein the first domain has a depth of greater than one cavity in three dimensions substantially throughout an entirety of the first domain" which is not required by the invention of group VI.

4. The inventions of groups (II, III, and IV) are distinct from one another. The inventions are drawn to distinct product compositions having distinct structural and functional components. The invention of group IV requires the components such as a housing, sensor head and electronic circuitry, which is not required by the inventions of groups II and III. The invention of group II as claimed, requires a sensor head suitable for use in an implantable device, which is not required by the invention of group III (as claimed; see recitation of instant claim 57).

5. The inventions of groups (VIII, VIII and IX) are distinct from one another. The inventions are drawn to distinct methods of monitoring or measuring analyte levels using an implantable device in a host. The inventions of groups (VIII and IX) are distinct from the invention of group VII because they require method steps of providing an implantable device comprising various components such as at least one sensor head, housing, electronic circuitry, etc, which is not required by the method of group VII. The processes of groups VIII and IX are distinct from each other because the method of group IX requires the method step of providing an implantable device "capable of accurate continuous analyte sensing" in a biological fluid, which is not required by the method of group VIII.

The inventions listed above are independent and distinct from one another as they have acquired a separate status in the art and require independent searches, particularly with regard to the literature searches. Clearly, a reference that would anticipate one of the above groups would not necessarily anticipate or even make obvious any of the others.

An undue burden would ensue from the examination of multiple methods, which have distinct steps and end points. Burden lies not only in the search of US Patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, scope of enablement, and double patenting issues.

Because these inventions are distinct for the reasons given above and the literature search required for one Group is not required for the other group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Specie Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

The following specie election is required:

Claims 20, 48, 76, 105, 132, 160, 179, 208, and 242, each recite following species:

polytetrafluoroethylene,

polyethylene-co-tetrafluoroethylene,

polyolefin,

polyester, and

polycarbonate

Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie (consistent with the respective group of the invention elected) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 1-19, 21-47, 49-75, 77-104, 106-131, 133-159, 161-178, 180-207, 209-241, and 243-250 are deemed to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitation of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35U.S.C. §§101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to maintain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**.

Further, note that the protection against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF (alternate Fridays OFF).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Satyendra K. Singh
Patent Examiner
Art Unit 1651

SANDRA E. SAUCIER
PRIMARY EXAMINER